1 INTRODUCTION

As part of an ongoing effort to increase the use of risk information in its regulatory activities, the U.S. Nuclear Regulatory Commission (NRC) High-Level Waste Program is enhancing documentation of risk information and synthesizing the information to better support a risk-informed regulatory program. This effort is referred to as the Risk Insights Initiative. This report documents the results of the Risk Insights Initiative and provides the results in the form of the Risk Insights Baseline Report. The Risk Insights Baseline Report serves as a common reference for the staff to use in risk-informing the NRC high-level waste program, as it continues through prelicensing regulatory activities and prepares to review a license application that may be submitted by the U.S. Department of Energy (DOE) for a potential high-level waste repository at Yucca Mountain, Nevada.

The system description and the risk insights presented in this report are intended to assist the staff in its prelicensing interactions with DOE and in reviewing any license application DOE may submit. Staff have not made any determinations regarding the technical conditions or the adequacy of a repository at Yucca Mountain at this time. If DOE submits a license application for a repository at Yucca Mountain, staff will review the information provided by DOE, and make its determinations based on information available at that time.

1.1 Background

In the Probabilistic Risk Assessment Policy Statement (60 FR 42622, August 16, 1995), NRC formalized its commitment to risk-informed regulation through the expanded use of probabilistic risk assessment in regulatory activities. In issuing the policy statement, NRC expected the implementation to improve the regulatory process in three ways: (i) incorporation of probabilistic risk assessment insights into regulatory decisions; (ii) conservation of Agency resources; and (iii) reduction of unnecessary burden on licensees. The Probabilistic Risk Assessment Policy Statement states, in part, "The use of probabilistic risk assessment technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in Probabilistic Risk Assessment methods and data, and in a manner that complements NRC deterministic approach and supports NRC traditional defense-in-depth philosophy."

In its staff requirements memorandum for COMSECY–96–061 (April 15, 1997), the Commission envisioned a risk-graded approach where the staff would use risk information to focus on those licensee activities that pose the greatest risk to the public health and safety, thereby accomplishing the NRC principal mission in an efficient and cost-effective manner. In general, activities of higher risk should be the primary focus of the DOE efforts and resources.

NRC defined the terms and expectations for risk-informed and performance-based regulation in a white paper staff requirements memorandum, Risk-Informed and Performance-Based Regulation (Staff Requirements Memorandum for SECY–98–144; March 1, 1999). The guidance was intended to ensure consistent interpretation of the terms and implementation of NRC expectations with respect to their use in regulatory activities. NRC believes that a risk-informed approach should use risk insights to focus regulatory attention on issues, commensurate with their importance to public health and safety. NRC also stated in the white paper that risk insights can make the elements of defense-in-depth, a fundamental tenet of nuclear regulatory practice, clearer by quantifying them to the extent practicable.

Building on approximately 20 years of performance assessment activities, the high-level waste program staff began the Risk Insights Initiative, in 2002, to improve integration and communication of the issues considered important to the performance of the high-level waste repository, thereby enhancing its ability to conduct a focused, risk-informed review of both issue resolution activities and ultimately the license application that the DOE is anticipated to submit for the proposed geologic repository at Yucca Mountain.

In response to a request from the Commission, the staff provided an initial draft of the Risk Insights Baseline Report to the Commission on June 5, 2003, along with an initial ranking of the risk significance of the key technical issue agreements. This report provides the supporting quantitative analyses and discussion of uncertainties for the risk insights.

1.2 Purpose of the Risk Insights Baseline Report

The primary purpose of the Risk Insights Baseline Report is to summarize the staff current understanding of how a repository system at Yucca Mountain might function to isolate waste and, thus, protect public health and safety during the compliance period. The Risk Insights Baseline Report outlines the staff current thinking of how the principal features, events, and processes that might be present at Yucca Mountain following permanent closure of the repository could affect the estimated risks to an individual in the vicinity of Yucca Mountain. The staff perspective presented in the baseline is drawn from experience gained through its independent technical analyses, reviews, and performance assessment activities, as well as through the extensive technical interactions with the DOE and other groups external to the Agency, that have been completed to date. The Risk Insights Baseline Report provides a common basis for the staff as it conducts its prelicensing regulatory activities regarding postclosure repository performance in a risk-informed manner.

Risk insights are the results and findings drawn from risk assessments. In the high-level waste program, risk insights help to convey the significance of specific features, events, and processes to waste isolation capabilities and calculated estimates of system risk. The high-level waste risk insights have been integrated into a baseline and presented in a way that enhances their communication and understanding among the staff and others, both inside and outside NRC. Although the significance of the risk insights may be expressed in somewhat qualitative terms (i.e., high, medium, and low significance), individual insights are supported by quantitative risk information derived from risk assessments and other technical analyses. The Risk Insights Baseline Report summarizes these supporting analyses and discusses the associated uncertainties.

1.3 Objectives of the Risk Insights Baseline Report

The format of the Risk Insights Baseline Report is intended to clearly communicate staff current understanding of the repository system, as supported by quantitative risk analyses. The baseline also discusses the relative uncertainties associated with the staff understanding. Finally, the baseline organizes the risk insights into a structure that readily supports risk-informing staff high-level waste regulatory activities. To this end, the report:

- Clarifies the application of risk insights in the high-level waste program
- Documents the baseline set of risk insights for the postclosure repository system, identifying the significance of the insights relative to waste isolation
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- Describes the quantitative analyses that support the risk insights
- Documents uncertainties associated with the baseline set of risk insights
- Discusses the application of the baseline set of risk insights to staff ongoing and future regulatory activities (e.g., issue resolution, license application review, etc.)

The individual risk insights were developed as concise statements to enhance their communication and comprehension. As stated, staff developed the risk insights by drawing on many years of technical analysis and risk assessment experience.

1.4 Scope of the Risk Insights Baseline Report

The Risk Insights Baseline Report presented in this report addresses staff current understanding of the repository system following cessation of repository operations and permanent closure of the repository through the 10,000-year compliance period (i.e., the postclosure period). This understanding is currently reflected, to a great extent, in the NRC Total-system Performance Assessment (TPA) computer code. The staff, together with the Center for Nuclear Waste Regulatory Analyses (CNWRA), have developed this computer code in support of prelicensing activities and potential review of a license application for a repository at Yucca Mountain. The Risk Insights Baseline Report presented in this report is drawn from staff experience gained through the development and exercise of the TPA code, technical analyses conducted by staff to support prelicensing interactions with DOE, and analyses conducted by DOE and others.

The Risk Insights Baseline Report presented in this report does not address staff current understanding of the risks associated with the operation of a repository before permanent closure (i.e., the preclosure period). The staff, together with CNWRA, are currently developing the Preclosure Safety Analysis Tool, a computer code that staff will use to support its review of preclosure safety issues. The Risk Insights Baseline Report is expected to be expanded at a later date, to make use of the Preclosure Safety Analysis Tool results.

This report directly addresses risk insights related to estimating potential dose to an individual during the postclosure period. Although risk insights related to ground water protection are not explicitly identified in this report, staff believe they would be adequately addressed by the insights provided in this report.

2 APPLICATION OF RISK TERMINOLOGY IN THE NRC HIGH-LEVEL WASTE PROGRAM

This chapter discusses the general application of risk terminology in the U.S. Nuclear Regulatory Commission (NRC) high-level waste regulatory program. The NRC white paper report, Risk-Informed and Performance-Based Regulation, is the basis for the risk terminology used in the high-level waste program. This section provides additional guidance on how the terms relate specifically to the Risk Insights Baseline Report.

On March 1, 1999, NRC approved issuing the Risk-Informed and Performance-Based Regulation white paper that outlines its expectations regarding the risk-informed and performance-based regulation of nuclear safety. The white paper defines these and other related terms in an effort to promote a more common understanding within NRC and its regulated community, as well as by the public, as to how risk-informed and performance-based concepts apply to various agency functions.

NRC advocates using risk-informed and performance-based approaches in developing and implementing regulations, and directs staff to increase its use of probabilistic risk assessment in all regulatory matters to the extent supported by the state-of-the-art in methods and data, and in a manner that complements NRC deterministic approach and supports NRC tradition of defense-in-depth. With respect to the high-level waste program, NRC promulgated its regulation at 10 CFR Part 63 after the issuance of the Probabilistic Risk Assessment Policy Statement. Consistent with this policy, the regulation at 10 CFR Part 63 is risk-informed. The regulation includes risk-based requirements, as well as deterministic and prescriptive requirements. The staff are currently focused on risk-informed implementation of the rule.

This section discusses the application of several of the terms from the white paper to the high-level waste Risk Insights Baseline Report. Much of the discussion has been taken directly from the white paper.

2.1 Risk

The definition for risk in the white paper takes the view that assessing risk involves three questions: What can go wrong?; How likely is it?; and What are the consequences? These three questions are referred to as the risk triplet. The traditional definition of risk, that is, probability times consequences, is fully embraced by the triplet definition of risk.

For the high-level waste postclosure repository system, the risk is usually expressed in terms of probability-weighted dose, for comparison to the dose-based individual protection standard.

2.2 Risk Assessment

The white paper defines risk assessment as a systematic method for addressing the risk triplet as it relates to the performance of a particular system (which may include a human component) to understand likely outcomes, sensitivities, areas of importance, system interactions, and areas of uncertainty. From this assessment, the important scenarios can be identified.

The method used to conduct a risk assessment depends on the particular system being

evaluated. In the high-level waste program, performance assessment is used to assess the risks associated with postclosure performance of a repository system. Consistent with the white paper definition, the performance assessment methodology includes not only the system-level analyses performed to calculate probability-weighted dose, but also the supporting analyses performed to understand system-level results, the sensitivities and uncertainties in the system-level results, the capability of individual system components and processes, and interactions among the components and processes. These supporting analyses use intermediate results from system-level computer codes as well as results from auxiliary calculations.

2.3 Risk Insights

The white paper defines the term risk insights as the results and findings that come from risk assessments. Risk insights may be explicitly expressed relative to system-level risk, such as probability-weighted dose. Risk insights also may be expressed in terms of surrogate measures, as long as the relationship between the surrogate measure and the system-level risk is understood. The extent to which risk insights are explicitly factored into the activities and decisionmaking of a specific regulatory program depends on the maturity of risk assessment methodologies and data for that program. Incorporating risk insights into a regulatory program is intended to improve both efficiency and effectiveness of the regulatory program.

In the high-level waste program, risk insights are based on the quantitative results of performance assessments. As previously defined, performance assessments include the quantitative analyses of system-level performance (e.g., analyses using the TPA code or simplified models that result in a calculation of probability-weighted dose) as well as supporting analyses (e.g., calculation of waste package failure rates, release rates of radionuclides from the waste package, and transport times of radionuclides to the compliance location) that help the staff understand the system-level results. Risk insights include the interpretation of, and the conclusions drawn from, the quantitative risk assessment results, relative to system-level risk (e.g., probability-weighted dose). Uncertainties in the risk estimates are addressed through the use of parameter ranges and alternative approaches and models.

The risk assessment methodologies applicable to the high-level waste program are relatively mature. Therefore, it is expected that high-level waste regulatory activities and decisionmaking will be guided by risk insights to a great extent, to improve effectiveness and efficiency.

2.4 Risk-Based and Risk-Informed Approaches

According to the white paper, a risk-based approach to regulatory decisionmaking is one in which such decisionmaking is solely based on the numerical results of a risk assessment. However, uncertainties in risk assessment methodologies and results limit the practicality and acceptability of purely risk-based regulatory decisionmaking. Because NRC does not endorse risk-based regulatory decisionmaking, regulatory decisionmaking in the high-level waste program will not be based solely on the quantitative results of risk assessments.

NRC endorses a risk-informed approach to regulatory decisionmaking, a philosophy whereby risk insights are considered, together with other factors, to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with

their importance to public health and safety. According to the white paper, a risk-informed approach enhances the deterministic approach, which requires safety systems capable of mitigating consequences of adverse conditions which are assumed to exist, by:

- Allowing explicit consideration of a broader set of potential challenges to safety;
- Providing a logical means for prioritizing these challenges, based on risk significance, operating experience, and/or engineering judgment;
- Facilitating consideration of a broader set of resources to defend against these challenges;
- Explicitly identifying and quantifying sources of uncertainty in the analysis (although such analyses do not necessarily reflect all important sources of uncertainty); and
- Leading to better decisionmaking by providing a means to test the sensitivity of the results to key assumptions.

Where appropriate, a risk-informed regulatory approach also can be used to reduce unnecessary conservatism in purely deterministic approaches, or can be used to identify areas with insufficient conservatism in deterministic analyses and provide the bases for additional requirements or regulatory actions. Risk-informed approaches lie somewhere on the spectrum between the risk-based and purely deterministic approaches, depending on the regulatory issue under consideration.

Risk insights make the elements of defense-in-depth more clear by quantifying them to the extent practicable. Risk insights related to the individual performance of each defense system, in relation to overall performance, support decisionmaking on the adequacy of, or the necessity for, elements of defense (see Section 2.5).

The high-level waste program will follow a risk-informed approach to support regulatory activities and decisionmaking with respect to the requirements of the regulation at 10 CFR Part 63. This approach will focus resources on issues commensurate with their importance to risk. This approach will take into account the quantitative risk insights, together with uncertainties and sensitivities, engineering judgment, and other relevant factors.

2.5 Risk-Informed Approach and Defense-in-Depth

The concept of defense-in-depth has always been, and will continue to be, a fundamental tenet of regulating nuclear facilities. Defense-in-depth is an element of NRC safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. For the postclosure repository system, the regulation at 10 CFR Part 63 incorporates the defense-in-depth concept through the multiple barriers requirements. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges. Risk insights can make the elements of defense-in-depth more clear by quantifying their significance to waste isolation to

the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can assist and support regulatory decisionmaking. Decisions on the adequacy of, or the necessity for, elements of defense-in-depth, should reflect risk insights gained through identification of the individual performance of each safety system in relation to overall performance.

3 DEVELOPMENT OF THE RISK INSIGHTS BASELINE REPORT

3.1 Background

The Risk Insights Initiative began in January 2002. The early efforts of the Risk Insights Initiative were aimed at enhancing communication, among the staff, of the more significant technical issues, and identifying and focusing the staff attention on the more significant of the prelicensing agreements that had been established between the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC). A facilitated approach was used during a series of meetings to develop a consensus, among the staff, of the significance of the 293 prelicensing agreements relative to the calculated system-level risk estimates. During these initial activities, consideration of risk was not limited to a quantitative, dose-based definition. Instead, the staff considered more subjective measures of risk as part of the enhanced communication effort.

The preliminary results of the initial Risk Insights Initiative exercise were presented to the Advisory Committee on Nuclear Waste in April 2002. The committee commented that the effort was successful as a communication exercise among the staff. However, the committee agreed with the staff plan for repeating the exercise, but emphasized that the staff should focus on quantitative health and safety risks.

Following these initial efforts, the staff adopted a more integrated and quantitative systems approach to evaluating the significance of the key technical issue agreements. The staff began to develop the Risk Insights Baseline Report, a concise description of how a potential repository system at Yucca Mountain might function during the postclosure period. The Risk Insights Baseline Report provided a system-level perspective on the relative significance of system features, events, and processes, by looking at how they might affect the waste isolation capabilities of the repository system during the postclosure period, and the potential effect on public health and safety. The staff could then relate the agreements to this integrated system-evel baseline to assess the relative significance of individual key technical issue agreements.

3.2 Development of the Current Baseline

The Risk Insights Baseline Report has been developed by synthesizing available information drawn from quantitative risk assessments. The insights are based on many years of experience with conducting total-system performance assessments, subsystems analyses, and auxiliary calculations. The insights are also based on the staff review and interpretation of the performance assessments and supporting analyses conducted by others. Generally, the staff are relying on their own analyses to develop the risk insights, however, the analyses of others are useful for identifying alternative approaches and models that differ from those used by the staff in its performance assessment analyses. Understanding the analyses of others (e.g., DOE) is especially useful in specific areas where the staff approach in its total-system performance assessment computer code differ significantly from the approach of others (e.g., matrix diffusion in the unsaturated zone, representation of climate change). An understanding of the analyses of others provides additional information to evaluate the strengths and limitations of the risk insights.

The staff started with a system-level perspective and worked down to levels of greater detail and specificity. To coordinate the development of the set of insights, and to facilitate application of the Risk Insights Baseline Report to the staff regulatory activities, the staff organized the risk insights around the postclosure performance assessment model abstractions, referred to as integrated subissues. These integrated subissues are identified in two other primary NRC documents related to the high-level waste program, NUREG–1762 (NRC, 2002) and NUREG–1804 (NRC, 2003).

Within each model abstraction, the staff developed individual risk insights to address the important components (i.e., features, events, and processes, both natural and engineered) of the repository system and to communicate how these components relate to waste isolation capability and to estimates of risk. Thus, the risk insights discussed in this report for the high-level waste program tie the system components to some potential effect on health and safety, in terms of dose. The staff did not attempt to develop risk insights to address all the components of a potential repository system at Yucca Mountain, but has, instead, focused on those the staff have identified as most important.

The risk insights are generally framed around the three aspects of the risk triplet. Each risk insight is stated in terms of a scenario, essentially as a statement of the feature, event, or process that might exist or occur. The baseline also provides context for understanding the likelihood that the scenario will exist or occur during the regulatory period of interest. The baseline also includes a discussion of the consequence of the scenario, in terms of its beneficial or adverse effect on the waste isolation capabilities of the repository system. An effect on waste isolation capability subsequently affects the estimated dose, or risk, to an individual.

Quantitative results for waste isolation capability (e.g., release rates from waste package, transport times for radionuclides) provide further insight to understand the effect on risk. Additionally, certain analyses were conducted beyond the regulatory period of 10,000 years to understand the sensitivity of repository performance to the timing of a process or event (i.e., when it occurs) that is currently estimated to occur beyond the compliance period (e.g., corrosion of the waste package, certain climate changes).

The baseline also provides an interpretation of the analyses to the extent necessary to explain the relationship between the analyses and the risk insight. These analyses generally have been excerpted from existing technical reports, papers, and presentations. The analyses address the likelihood of the condition described in the insight occurring at the site during the period of regulatory interest, or the consequence if the condition were to occur. Although development of the risk insights was based primarily on quantitative, system-level risk analyses, such as performance assessment calculations, the analyses include all of the supporting evidence that is used to build confidence in the calculations and the safety attributes of the repository system. Such evidence may include information from laboratory and field experiments, natural or human-induced analogs, sensitivity analyses, and other specialized analyses at a subsystem level.

For each risk insight, the baseline also provides a discussion of the uncertainties associated with the analyses and their interpretation. Uncertainties are inherent in any attempt to characterize, understand, and model the future behavior of a natural or engineered system. Therefore, it is important that a discussion of the staff current state of knowledge and understanding of the functioning of the repository system considers uncertainties. This includes

data and model uncertainties, as well as uncertainties associated with the combined effects of scenarios. Generally, important uncertainties for estimating repository performance are addressed in the current analyses through a variety of approaches such as use of parameter ranges (e.g., range of retardation factors of radionuclides in alluvium) and conservative modeling approaches (e.g., assume southerly blowing wind direction for igneous activity). The discussion of uncertainties primarily provides insight where increased realism would reduce uncertainty in performance estimates. Because the approaches in the staff TPA computer code tend to be conservative when the uncertainty is large, improved realism is generally expected to reduce the current estimate of risks.

The staff plan to use the Risk Insights Baseline Report to help prioritize its prelicensing activities, focus staff resources, and support risk-informed project management and decisionmaking in the high-level waste program, during prelicensing activities and during the review of a potential license application for a Yucca Mountain repository. To support this intended application of the Risk Insights Baseline Report, the staff grouped the risk insights into three categories of relative significance (high, medium, and low) based on contribution to, or effect on, the waste isolation capabilities of the repository system.

Although individual risk insights are supported by quantitative analyses, classifying the risk insights by relative significance to waste isolation is more qualitative. Staff judgment was used, as needed, when combining information from different analyses. Significance is evaluated relative to the waste isolation capabilities of the repository system. Three criteria were considered in evaluating the significance of the risk insights:

- Effect on the integrity of waste packages;
- Effect on the release of radionuclides from the waste form and waste package; and
- Effect on the transport of radionuclides through the geosphere and biosphere.

In general, high significance is associated with features, events, and processes that could: (i) affect a large number of waste packages, (ii) significantly affect the release of radionuclides, or (iii) significantly affect the transport of radionuclides through the geosphere or biosphere. Medium significance is associated with a lesser effect on waste packages, radionuclide releases, or radionuclide transport, and low significance is associated with no or negligible effect.

3.3 Multiple Barriers

Integral to developing the risk insights is the concept of multiple barriers (i.e., both engineered and natural barriers) in geologic disposal of high-level waste. For example, the safety of geologic disposal is enhanced if the system includes: (i) a long-lived waste package that retains its integrity during the period of the highest thermal output of the waste when the waste-form behavior is most uncertain because of potentially high temperatures, (ii) slow release rates of radionuclides from the engineered barrier system once the waste packages are breached, and (iii) slow travel of released radionuclides from the engineered barrier system to the area where potential exposures might occur. Multiple barriers, as an element of a defense-in-depth approach, result in a robust repository system that is more tolerant of failures and external challenges (e.g., poor or highly degraded performance is necessary in multiple areas to have a significant effect on risk). The risk insights are developed within the multiple barrier context (i.e., understanding the significance to waste isolation of the long-lived waste package, release rates of radionuclides, and transport of radionuclides in the context of the effect on risk estimates).